Introduced by Assembly Member Ting

February 27, 2015

An act to amend Section 4076.5 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1073, as introduced, Ting. Pharmacy: prescription drug labels. The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. That law requires the board to promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California. Existing regulations of the board implement that requirement.

This bill would remove that obsolete date.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

- SECTION 1. Section 4076.5 of the Business and Professions 1 2 Code is amended to read:
- 3 4076.5. (a) The board shall promulgate regulations that require,
- on or before January 1, 2011, require a standardized, 4
- 5 patient-centered, prescription drug label on all prescription
- medicine dispensed to patients in California. 6
- 7 (b) To ensure maximum public comment, the board shall hold
- public meetings statewide that are separate from its normally

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scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

- (c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:
- (1) Medical literacy research that points to increased understandability of labels.
 - (2) Improved directions for use.
 - (3) Improved font types and sizes.
- (4) Placement of information that is patient-centered.
- 12 (5) The needs of patients with limited English proficiency.
 - (6) The needs of senior citizens.
 - (7) Technology requirements necessary to implement the standards.
 - (d) The board may exempt from the requirements of regulations promulgated pursuant to subdivision (a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.
 - (e) (1) The board may exempt from the—requirements—of regulations promulgated pursuant to subdivision (a) a prescription dispensed to a patient if all of the following apply:
 - (A) The drugs are dispensed by a JCAHO-accredited home infusion or specialty pharmacy.
 - (B) The patient receives health-professional-directed education prior to before the beginning of therapy by a nurse or pharmacist.
 - (C) The patient receives weekly or more frequent followup contacts by a nurse or pharmacist.

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(D) Care is provided under a formal plan of care based upon a

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physician and surgeon's orders.

(2) For purposes of paragraph (1), home infusion and specialty therapies include parenteral therapy or other forms of administration that require regular laboratory and patient monitoring.